DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 00-NWJ-31

May 8, 2000

Larry Bandi
President and Chief Executive Officer
Valley National Gases, Inc.
67 43rd Street
Wheeling, WV 26003

Dear Mr. Bandi:

During an inspection of your medical nitrogen and oxygen repackaging facility, located at 201 Crown Point Road, Thorofare, NJ 08086, from March 14-22, 2000, our investigator documented deviations from Current Good Manufacturing Practices for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211). These deviations cause your drug products, Nitrogen NF and Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). Our investigator also documented deviations from the Drug Labeling regulations (Title 21, Code of Federal Regulations, Part 201) which cause your Liquid Oxygen, USP product to be misbranded within the meaning of Section 502 of the Act.

Those deviations included:

- The filling system for Nitrogen, NF is not dedicated to filling that single gas. This procedure necessary to ensure that cross-contamination of the Nitrogen with other industrial gases you fill at your facility does not occur. In addition, the non-dedicated filling equipment is not cleaned in between filling operations *[21 CFR 211.130 & 211.67].*

- Failure to validate the Servomex 570A paramagnetic analyzer for the testing of Nitrogen, NF *[21 CFR 211.100].*

- Cryogenic vessels containing Liquid Oxygen, USP are not fitted with connections to ensure only Oxygen may be filled into those units *[21 CFR 211.130].*

- Cryogenic vessels containing Liquid Oxygen, USP are not properly labeled to indicate the drug product, manufacturer's/distributor's name and address, lot number, and adequate directions for use *[21 CFR 201.01, 201.05, 201.10 & 211.130(c)]*.

- Personnel involved in the filling, testing, labeling, holding and distribution of medical gas products have not been trained in Current Good Manufacturing Practices to assure those persons are qualified to perform those operations *[21 CFR 211.25]*.

The above deviations are not intended to be an all-inclusive list of violations. As a repackager of drug products for human use, you are responsible for assuring that your overall operation and the products you distribute are in compliance with the law.

We acknowledge receipt of your April 13, 2000 written response to the District and commitments made to the investigator at the time of the inspection, including cessation of Nitrogen, NF transfilling operations at your Thorofare, NJ location.

You should take prompt action to correct any remaining violations of the Act and to establish procedures whereby such violations of the Act do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction. Please advise this office, within 15 days of receipt of this letter, of any additional actions you have taken or plan to take to correct those violations.

By copy of this letter, we are advising the U.S. Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Food, Drug and Cosmetic Act. They may elect to defer or discontinue payment for any health care product in violation of State or Federal law.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

Douglas I. Ellsworth

Douglas I. Ellsworth
District Director